Remarks

The present communication responds to the non-Final Office action of April 9, 2007 in which the Examiner rejected claims 2-14, 16 and 17. Claims 2-9 remain withdrawn from consideration. Claims 10-14, 16 and 17 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent 6,120,492 ("Finch et al.").

The claim rejections are traversed for at least the reasons articulated below and reconsideration is requested.

Claim Rejections Under 35 USC § 102

Claims 10-14, 16 and 17 were rejected under 35 U.S.C. § 102(e) as anticipated by Finch et al.

This rejection is traversed for at least the following reasons.

Claim 10 is directed to a cannula/needle combination for a catheter head for administering a fluid substance, including a needle including a substantially sharpened piercing end, and a cannula surrounding the needle in a snug fit between an inner wall of the cannula and an outer wall of the needle, wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow, wherein the cannula/needle combination is assembled prior to use.

Claim 16 is directed to a method for administering a fluid substance including, inserting a pre-assembled cannula/needle combination by piercing the skin with the needle in cannula/needle combination, wherein the pre-assembled cannula/needle includes a needle comprising a substantially sharpened piercing end, and a cannula surrounding the needle in a snug fit between an inner wall of the cannula and an outer wall of the needle; wherein a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow.

Claim 17 is directed to a system for providing a cannula/needle combination for a catheter head for administering a fluid substance, including piercing means for piercing the skin, wherein the piercing means includes at least a substantially sharpened piercing end, fluid delivery means for administering a fluid substance, wherein the fluid delivery means at least surrounds said piercing means and forms a snug fit between an inner wall of the fluid delivery means and an outer wall of the piercing means, wherein the piercing means and fluid delivery means are pre-assembled before piercing the skin, and wherein a clearance is configured between the inner wall of the fluid delivery means and the outer wall of the piercing means, the fluid substance communicated in the clearance, thereby delivering the fluid without the piercing means being necessarily hollow.

Finch et al. discloses methods and apparatus for percutaneously accessing an implanted port using an access cannula which is periodically introduced to an aperture on an implanted port so that the cannula passes through the same tissue tract. (*See Finch et al., abstract.*)

It is asserted in the Office Action that although Finch et al. may disclose using an access cannula which just uses the access needle itself as a penetrating element without utilizing a stylet does not overcome the fact that Finch et al. also disclose in Figure 3a an embodiment in which a stylet is used.

In Figure 3a, Finch et al. shows a stylet. However, Finch et al. does not disclose that a clearance is configured between the inner wall of the cannula and the outer wall of the needle, the fluid substance communicated in the clearance, thereby delivering the fluid without the needle being necessarily hollow as recited in claims 10 and 16, or that a clearance is configured between the inner wall of the fluid delivery means and the outer wall of the piercing means, the fluid substance communicated in the clearance, thereby delivering the fluid without the piercing means being necessarily hollow as recited in claim 17.

To the contrary, Finch et al. discloses an embodiment shown in Figure 3a, wherein

> [a] penetrable seal 128 is positioned at the upper end of the passage 118 and permits removable entry of a stylet 130 having a sharpened distal end 132 which extends through the blunt end 122 of cannula 120. The stylet includes a handle

> 134 at its proximal end to permit removal the stylet after the cannula 120 has been introduced through a tissue tract to an implanted port. *(Finch et. al., col. 9, lines 13-19.)*

The stylet 130 is removed by a handle. (*See also, Finch et al., FIG. 3a*). The stylet is utilized for initial tract formation. The stylet is subsequently removed, to allow for blood or other fluids to be exchanged. Finch et al. does not disclose a clearance configured between the inner wall of the cannula and the outer wall of the needle, which would permit the stylet to be left in place for such fluid exchange.

Finch et al. prefers use of an access cannula (16') which just uses access needle 20 itself used as a penetrating element without utilizing a stylet as in FIG. 3a. (*Cf. Finch et. al. FIGS. 3 and 3a.*)

> A tissue penetrating element, which may be a needle, rod, stylet, tube, or virtually any other penetrating element, may then be introduced through the intact region of skin IR, as shown in FIG. 4G. In FIG. 4G, an access cannula 16' is used as the penetrating element, but it will be appreciated that this is not necessary for initial tissue tract formation. It is preferable, however, since use of an access cannula permits blood or other fluids to be exchanged through the implanted port from a time very shortly after implantation of the port. The penetrating element will be left in place transcutaneously through the skin for a time sufficient to at least begin forming the tissue tract, usually for at least one week, preferably for at least two weeks. After that initial time, the tissue penetrating element may be removed and the resulting tissue tract accessed using access cannulas according to the method of the present invention described above. (*Finch et al., col. 10, lines 50-59; see also, FIGS. 3 and 4G.*)

Not using the stylet is preferred, "since use of an access cannula *permits blood or other fluids to be exchanged* through the implanted port from a time very shortly after implantation of the port." (*Finch et al., col. 10, lines 56-57 (emphasis added).*) Therefore, the stylet/access cannula combination of Finch et al. does not include a clearance configured between the inner wall of the cannula and the outer wall of the needle.

For at least the preceding reasons, the rejection of claims 10, 16 and 17 under 35 U.S.C. § 102(e) should be reconsidered and withdrawn.

Rejection of the Dependent Claims

Because claims 11-14 depend directly from independent claim 10, and incorporate all the limitations of the corresponding independent claim 10, they are allowable for the same reasons and, further, in view of their additional recitations.

Conclusion

This response is being submitted on or before October 9, 2007, with the required fee of $1,050.00 for a three-month extension of time, making this a timely response. It is believe that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

The application is in allowable form, and reconsideration and allowance are requested.

Respectfully submitted,

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